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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,538	01/23/2001	Yingjian Wang	17281/00002	2993

7590 05/03/2005

EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 05/03/2005

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/767,538	WANG ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46 and 49-56* is/are pending in the application.

4a) Of the above claim(s) *1-36,40-42 and 50-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-39,43-46,49 and 53-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/9/04 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

Claims 1-46 and 49-56 are currently pending.

Claims 37-39, 43-46, 49 and 53-56 are under consideration.

Claims 1-36, 40-42 and 50-52 are withdrawn from consideration as being directed to a nonelected invention.

Election/Restrictions

Applicant's election with traverse of Group III (claims 37-49) in Paper No. 5 is acknowledged. Applicant's further election of

a. DNA (as specific type of reagent); and

b. Supports (claims 43-45; as barrier species

which reads on claims 37-39, 43-46, 49 and 53-56.

The requirement (as modified above) was previously made FINAL.

3. Claims *1-36, 40-42 and 50-52* are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Withdrawn Objection(s) and/or Rejection (s)

Upon further consideration applicant's arguments and amendment were found persuasive with regard to the following prior art rejections:

The separate prior art rejections over the Chin et al. and Shalon et al. WO 95/35505 (12/95) references which fail to teach "dissociation" and "transfer" of the reagents to the corresponding biological target.

The Sabatini art rejection has been modified in response to applicant's amendment and arguments already of record.

Outstanding Objection (s) and/or Rejection (s)

4. Claims 54-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Sabatini US Pat. No. 6,544,790 (4/03: filed 9/99).

Claim 54 is drawn to a method of contacting 2 or more reagents with 1 or more biological targets comprising:

a. providing an array of 2 or more reagents;

b. providing 1 or more biological targets *on said array* and "contacting" the target(s) with 1 or more reagent(s);

c. applying 1 or more "conditions";

d. 1 or more ("some or all") reagent(s) "dissociate" from its array and "transfers" to a "corresponding biological target".

Sabatini teaches both a method and apparatus for making (micro)arrays comprising "two or more reagents" (e.g. DNA/RNA: bottom of col. 1 to top of col. 2) and "one or more barriers ... wherein each portion is maintained at predefined positions ... portions is adapted to be brought into contact with one or more predefined biological targets" in which the "barrier" comprises a "solid support" (e.g. any "flat surface" including slides made of glass, polystyrene, plastic,, microtiter plates etc. which can be polymer coated e.g. with polylysine; or bottom of wells in multi-welled plates: see col. 2; 10, 16). The Sabatini reference further teaches "providing one or more biological targets" which include cells grown on "growth supports" and/or applied (seeded/adhered) to the DNA/RNA reagent while employing growth medium (DMEM) (e.g. see col. 4;). The Sabatini reference further teaches the making of support immobilized addressable targets (e.g. cells) within the scope of the presently claimed invention (e.g. ... "distinct and defined areas of a lawn of cells": see col. 14, especially lines 13-16 and figures especially fig. 4a) for transfection with arrayed DNA (e.g. transfer of reagent DNA to target cell). The Sabatini reference method further teaches the use of "one or more conditions" to promote transfection (e.g. see col. 1, especially lines 30-40) including electroporation (e.g. electric pulse) as a condition to facilitate transfer (e.g. transfection) of the DNA/RNA into the target cell (s). See also figures and patent claims. It is noted that the Sabatini reference teaches DNA spotting (e.g. see col. 5) e.g. a "lipid-DNA embodiment" and "gelatin DNA" embodiment utilizing supports (e.g. slide) and modification thereof (e.g. using polylysine) within the scope of the presently claimed invention to result in transfection which requires the "transfer" of

reagent DNA to cellular (e.g. eukaryotic: see col. 2) target thus rendering "dissociation from the barrier (e.g. reagent support) necessarily inherent.

New Objection (s) and/or Rejection (s)

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 37-39, 43-46, 49 and 53-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (NEW MATTER REJECTION).

A. In claims 37, 53 and 54 (and claims dependent thereon), the term "providing one or more said biological targets on a *target support*" ; "biological target immobilized on said target support"; "*target support*" and "*separating said target support from said array*"; to the extent that the "support" (which is broadly defined for immobilizing the reagent) is broader than "growth support" the increase in breadth beyond growth support constitutes new matter. Additionally, separating "target supports" from the array is not described. In applicant's amendment, Applicant has failed to indicate where said support exists.

B. In claims 37 and 54 (and claims dependent thereon), the phrase "applying one or more conditions" to the extent that this term is broader than "applying one or more conditions to one or more of said reagent portions to facilitate ... transfer ...reagent portions ... to corresponding target" the increase in breadth constitutes new matter. In other words the application of one or more conditions is limited to its specifically described purpose (e.g. as described and originally claimed e.g. see original claim 48). In applicant's amendment, Applicant has failed to indicate where said support exists.

C. In claims 37 and 54 (and claims dependent thereon) the phrase "... *dissociates* from said barriers ..." does not find specification or original claim support. In fact, the specification indicates (e.g. in non-transfection embodiments) that covalent or strong non-covalent reagent immobiliation is desirable (e.g. see bottom of specification page 20 to page 21). In this regard, the claim is NOT limited to DNA or Transfection, but reads on any reagent or assay embodiment. In applicant's amendment, Applicant has failed to indicate where said support exists.

Claim Rejections - 35 USC § 102/ §103

7. Claims 37, 43-46 and 53-55 are rejected under 35 U.S.C. 102(a,b,e) as being anticipated by Palsson US Pat. 5,811,274 (9/98).

Claim 54 is drawn to a method of contacting 2 or more reagents with 1 or more biological targets comprising:

a. providing an array of 2 or more reagents;

b. providing 1 or more biological targets on said array and "contacting" the target(s) with 1 or more reagent(s);

c. applying 1 or more "conditions";

d. 1 or more ("some or all") reagent(s) "dissociate" from its array and "transfers" to a "corresponding biological target".

Claim 37 further requires that:

a. the biological target is attached (e.g. immobilized) to a "target support"

b. designating an address for both the reagents and for the target(s); and

c. "corresponding" (prior to "contacting") 1 or more reagent(s) to 1 or more targets based on the designated reagent/target addresses.

Palsson teaches a method of contacting 2 or more reagents with 1 or more biological targets comprising:

a. providing an array of 2 or more reagents (e.g. "particles": see col.4 and patent claims) on a coated (e.g. polylysine) or uncoated "support" (e.g. cell growth support: see col. 5, especially lines 38- including membranes i.e. porous).

b. providing 1 or more biological targets (e.g. eukaryotic cells: see col. 5) for contacting the reagent array in which the 'biological targets" can be "localized" for contacing and/or immobilized (e.g. attached) to a support (e.g. see col. 3, especially lines 30-40);

c and d.. applying 1 or more "conditions" to promote contact, dissociation and transfer (e.g. transfection) (e.g. see bottom of col. 7-col. 8) of the particle DNA into the cell(s) into the corresponding target cell(s). See also examples and patent claims.

The reference provides for the separation of the reagent array from the target.

The reference examples illustrate the monitoring of transfection efficiency through assays requiring the designation and corresponding of array locations spacially for both the reference reagent and target (if immobilized).

8. Claims 37-39, 43-46, 49 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palsson US Pat. 5,811,274 (9/98) in view of Sabatini US Pat. No. 6,544,790 (4/03: filed 9/99).

The Palsson reference teaching discussed above is hereby incorporated by reference in its entirety.

The Palsson reference teaching differs from the presently claimed invention by failing to teach applying electric impulses (e.g. elecroporation) to the reagent as one of the conditions (e.g. present claims 49 and 56).

Electroporation is a conventional means of promoting transfection as illustrated by the Sabatini reference (e.g. see col. 1, especially lines 30-40).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Palsson reference (see Paulson at col. 8: which incorporated "standard" tranfection conditions) in order to further promote transfection efficiency.

9. Claims 37-39, 43-46, 49 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabatini US Pat. No. 6,544,790 (4/03: filed 9/99) in view of Palsson US Pat. 5,811,274 (9/98) and/or Lockett et al. US Pat. No. 5,854,224 (12/98).

Claim 54 is drawn to a method of contacting 2 or more reagents with 1 or more biological targets comprising:

a. providing an array of 2 or more reagents;

b. providing 1 or more biological targets on said array and "contacting" the target(s) with 1 or more reagent(s);

c. applying 1 or more "conditions";

d. 1 or more ("some or all") reagent(s) "dissociate" from its array and "transfers" to a "corresponding biological target".

Claim 37 further requires that:

a. the biological target is attached (e.g. immobilized) to a "target support"

b. designating an address for both the reagents and for the target(s); and

c. "corresponding" (prior to "contacting") 1 or more reagent(s) to 1 or more targets based on the designated reagent/target addresses.

Sabatini teaches both a method and apparatus for making (micro)arrays comprising "two or more reagents" (e.g. DNA/RNA: bottom of col. 1 to top of col. 2) and "one or more barriers ... wherein each portion is maintained at predefined positions ... portions is adapted to be brought into contact with one or more predefined biological targets" in which the "barrier" comprises a "solid support" (e.g. any "flat surface" including slides made of glass, polystyrene, plastic,, microtiter plates etc. which can be

polymer coated e.g. with polylysine; or bottom of wells in multi-welled plates: see col. 2; 10, 16). The Sabatini reference further teaches "providing one or more biological targets" which include cells grown on "growth supports" and/or applied (seeded/adhered) to the DNA/RNA reagent while employing growth medium (DMEM) (e.g. see col. 4;). The Sabatini reference further teaches the making of support immobilized addressable targets (e.g. cells) within the scope of the presently claimed invention (e.g. ... "distinct and defined areas of a lawn of cells": see col. 14, especially lines 13-16 and figures especially fig. 4a) for transfection with arrayed DNA (e.g. transfer of reagent DNA to target cell). The Sabatini reference method further teaches the use of "one or more conditions" to promote transfection (e.g. see col. 1, especially lines 30-40) including electroporation (e.g. electric pulse) as a condition to facilitate transfer (e.g. transfection) of the DNA/RNA into the target cell (s). See also figures and patent claims. It is noted that the Sabatini reference teaches DNA spotting (e.g. see col. 5) e.g. a "lipid-DNA embodiment" and "gelatin DNA" embodiment utilizing supports (e.g. slide) and modification thereof (e.g. using polylysine) within the scope of the presently claimed invention to result in transfection which requires the "transfer" of reagent DNA to cellular (e.g. eukaryotic: see col. 2) target thus rendering "dissociation from the barrier (e.g. reagent support) necessarily inherent. Following transfection, the slide may be removed for further processing (e.g. "separating target support from said array" claim 53). See e.g.examples.

The Sabatini reference differs from the presently claimed invention by plating the "target" cells directly onto the "reagent" (array) without the use of a "target" support.

However, the Lockett reference teaches a transfection method (e.g. see TRANSFECTION example col 12-13) which formulates a target cell array (e.g. 8x9 array of wells in a microtiter dish seeded with cells) prior to DNA transfection in order to locate the cell in a spatially positioned (e.g. address) manner for ease of identification.

Alternatively, the Palsson reference teaches a method of promoting transfection efficiency by providing a reagent array (e.g. "particles" comprising DNA) and target cells attached to supports (e.g. see col. 3) as compared to prior art "indirect methods" which require random contact between DNA containing "particles" and target cells. More specifically, Palsson teaches a method of contacting 2 or more reagents with 1 or more biological targets comprising: a. providing an array of 2 or more reagents (e.g. "particles": see col.4 and patent claims) on a coated (e.g. polylysine) or uncoated "support" (e.g. cell growth support: see col. 5, especially lines 38- including membranes i.e. porous); b. providing 1 or more biological targets (e.g. eukaryotic cells: see col. 5) for contacting the reagent array in which the 'biological targets" can be "localized" for contacing and/or immobilized (e.g. attached) to a support (e.g. see col. 3, especially lines 30-40); c and d.. applying 1 or more "conditions" to promote contact, dissociation and transfer (e.g. transfection) (e.g. see bottom of col. 7-col. 8) of the particle DNA into the cell(s) into the corresponding target cell(s). See also examples and patent claims. The Palsson reference provides for the separation of the reagent array from the target; and the reference examples illustrate the monitoring of transfection efficiency through assays requiring the designation and corresponding of array locations spacially for both the reference reagent and target (if immobilized).

Accordingly, the Lockett and Palsson reference taken separately or in combination provide motivation to one of ordinary skill in the art to modify the Sabatini method by utilizing a target support in order to:

a. spacially address the target for improved identification (e.g. with the reagent) as taught by Lockett; and/or

b. to improve transfection efficiency as taught by Palsson.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Sabatini reference to utilize a target attached to a support for purposes of improving assay identification and/or promoting transfection efficiency.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
April 29, 2005